

### **REMARKS**

This paper is filed in response to the Office action mailed on December 20, 2006. In the Office action, claims 22-41 are subjected to a restriction requirement. In response, applicant has cancelled claims 39-41, each directed toward a kit comprising syringe and non-hydrated pledget, and has added new claim 42, which depends from claim 22. As a result, claims 22-38 and 42 are currently pending and at issue.

In the Office action, claims 22-38 are rejected under 35 U.S.C. § 112, first paragraph; claims 23 and 34-38 are rejected under 35 U.S.C. § 112, second paragraph; and claims 22-38 are rejected under 35 U.S.C. § 103(a) as being obvious in view of prior art. In response, applicant has amended claims 22, 24-25, and 34, and has added new claim 42. In view of the amendments and remarks provided herein, applicant respectfully submits that all of the aforementioned rejections are overcome for reasons stated in the paragraphs that follow.

#### **Rejections Under 35 U.S.C. § 112, First Paragraph**

Claims 22-38 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. More specifically, the Examiner asserts that the aforementioned claims contain subject matter that was not described in the specification in such a way as to convey to one skilled in the art at the time of the application that the applicant had possession of the claimed invention because the specification does not disclose that the wetting agent “facilitate spreading and penetration of an aqueous solution into the gelatin sponge thereby decreasing a hydration time of the gelatin sponge”, as specified in independent claim 22.

Applicant respectfully disagrees. It is well established that the specification need not reproduce the exact language of the claims to satisfy the written description requirement of 35 U.S.C. § 112, first paragraph. In *re Wright*, 9 U.S.P.Q.2d 1649, 1651 (Fed. Cir. 1989) (“the claimed subject matter need not be described in haec verba in the specification in order for that specification to satisfy the description requirement”). According to Merriam-Webster online dictionary, a wetting agent is “a substance that by becoming adsorbed prevents a surface from being repellent to a wetting liquid and is used especially in mixing solids with liquids or *spreading liquids on surfaces*” (emphasis added). Moreover, according to paragraph [0046] of the published application, the wetting agent “facilitates or enhances the hydration or lubrication

of a hemostatic sponge”. As a result, applicant respectfully submits that a person of ordinary skill in the art would be well aware of, and fully appreciate, the function of the wetting agent and its application in the gelatin composition specified in claim 22. Nevertheless, applicant has amended claim 22 to simply specify that the wetting agent decreases hydration time of the gelatin sponge, which is clearly supported by the specification (paragraph [0046] and Table 2 of the published application). Therefore, this rejection should be withdrawn.

Moreover, the Examiner asserts that claim 34 includes new matter by specifying steps of “providing an aqueous solution” and “contacting the gelatin composition with the solution”. Again, applicant respectfully disagrees. As stated above, specification need not reproduce the exact language of the claims to satisfy the written description requirement of 35 U.S.C. § 112, first paragraph. The specification of the instant application discloses the soaking or dropping of the gelatin composition in RO water or tap water (paragraph [0110], [0116], [0117], and 0130] of the published application). Applicant respectfully submits that a person of ordinary skill in the art would understand that RO and tap water are examples of aqueous solutions, and therefore would be able to use the teachings of the specification to fully appreciate the steps of “providing an aqueous solution” and “contacting the gelatin composition with the solution”. As a result, applicant respectfully submits that this rejection is traversed and should be withdrawn.

The Examiner further asserts that the “anionic surfactant” specified in claim 24 is not described in the specification. Applicant has hereby amended claim 24 to replace the “anionic surfactant” with “anionic wetting agent”, which is consistent with, and sufficiently supported by, the specification (paragraph [0081] of the published application). Applicant respectfully submits that claim 24 as amended finds sufficient support in the specification. Accordingly, this rejection should be withdrawn.

Finally, the Examiner asserts that applicant has not disclosed that “the gelatin composition comprises from about 0.01 to about 5 wt% of the wetting agent” as specified in claims 27 and 37. However, the Examiner later stated that “[o]n last line of the page 9 and lines 1-2 of page 10 applicants disclosed that the gelatin composition from about 0.01 to about 5 wt% of the wetting agent after evaporation of the liquid solvent”. Applicant respectfully submits that this description indeed provides sufficient antecedent basis for the subject matter specified in claims 27 and 37, as the gelatin composition specified in both of those claims comprises a

coating of the wetting agent, which would not exist until after the final step of the manufacturing, i.e. “after evaporation of the liquid solvent”. Therefore, claim 27 and 37 are consistent with, and sufficiently supported by, the description provided on the last line of page 9 and lines 1-2 of page 10 of the original application. In fact, the description of “evaporation of the liquid solvent” is merely included in the description to differentiate the content of the wetting agent based on the gelatin composition from the content of the wetting agent “based on the total weight of the *applied solution*” that is described earlier on lines 24-28 of page 9 of the original application. Applicant respectfully submits that this rejection is traversed and should be withdrawn.

In light of the foregoing, applicant respectfully submits that all currently pending claims 22-38, and 42 comply with the written description requirement.

#### **Rejections Under 35 U.S.C. § 112, Second Paragraph**

Claims 25 and 34-38 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctively claim the subject matter which applicant regards as the invention. More specifically, the Examiner asserts that claim 25 specifies a broad range or limitation (polyoxyalkylenes) together with a narrow range or limitation (ether capped polyoxyalkylenes and ester capped polyoxyalkylenes) that falls within the broad range or limitation, which is considered indefinite. In response, applicant has amended claim 25 to remove “polyoxyalkylenes” from the Markush group, and added a new claim 42 to recapture this element. Both of those claims are now consistent with and supported by the specification (paragraph [0046] of the published application). As a result, applicant respectfully submits that both the amended claim 25 and the new claim 42 are now definite. Accordingly, this rejection should be withdrawn.

Moreover, claim 34 is rejected as being incomplete for omitting essential structural cooperative relationships of elements. More specifically, the Examiner asserts that the relationship of the steps of “providing an aqueous solution” and “contacting the gelatin composition with the aqueous solution” to the method for decreasing hydration time of the gelatin composition, is omitted. As stated above, the amended claim 34 as well as claims 35-38 depended thereupon no longer specify the aforementioned steps. Therefore, this rejection is moot and should be withdrawn.

In light of the foregoing, applicant respectfully submits that all currently pending claims 22-38, and 42 are sufficiently definite.

**Rejections Under 35 U.S.C. § 103(a)**

Turning to the prior art rejections. Claims 22-29 and 34-38 are rejected under 35 U.S.C. § 103(a) as being allegedly obvious over Japanese Patent No. 02-182259 (“Yasushi”). The Examiner asserts that the difference between Yasushi and the instant application is that Yasushi does not teach coating of the wetting agent on the surface of the cross-linked gelatin. Applicant concurs. Secondly, the Examiner asserts that because Yasushi discloses the soaking of a gelatin sponge in a cross-linking solution, i.e. wetting agent, the product of this process would include some wetting agent on the surface after drying, which reads on coating.

Applicant, however, respectfully disagrees with the second assertion. Yasushi discloses a hemostatic sticking plaster. According to the last paragraph of page 4 of Yasushi, the plaster is formed by: (1) adding a surfactant to an aqueous solution of gelatin; (2) stirring the solution to form a foam and freeze-drying the foam to obtain a sponge; and (3) soaking the sponge in an organic solvent solution containing a cross-linking agent in order to cross-link the gelatin or the like.

Contrary to the Examiner’s second assertion, applicant respectfully submits that the cross-linking solution disclosed in Yasushi is not a wetting agent. According to Yasushi, the cross-linking solution is “an organic solvent solution of a cross-linking agent to cross-link the sponge”, wherein the cross-linking agent is “any cross-linking agent normally used for cross-linking (e.g., aldehyde materials, glycidyl ether materials, isocyanate materials. etc.)”. The wetting agent specified in the currently pending claims of the instant application, on the other hand, is “a biocompatible agent which facilitates or enhances the hydration of lubrication of a hemostatic sponge” (paragraph [0046] of the published application), which is simply irrelevant to creating any covalent bonds, and therefore should not be responsive to the cross-linking agent or the cross-linking solution. Moreover, none of the exemplary cross-linking agents corresponds to the wetting agent disclosed in the instant application. Applicant respectfully submits that, contrary to the Examiner’s second assertion, Yasushi does not teach or suggest the soaking of a

cross-linked gelatin sponge in a wetting agent, much less the coating of a cross-linked gelatin with same.

Secondly, the Examiner asserts that "the presence of the wetting agent as a coating on the surface does not impart patentability of the claims. Again, applicant respectfully disagrees.

Under MPEP § 2142,

"[t]o establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure." *Citing, In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); *see also* MPEP § 2143-§ 2143.03 for decisions pertinent to each of these criteria.

As discussed above, Yasushi does not teach the coating of the gelatin sponge with a wetting agent. Moreover, Yasushi does not teach anything about the hydration time of the gelatin sponge, much less the method of reducing same. As a result, there is no suggestion or motivation to modify the gelatin sponge of Yasushi to include a coating of a wetting agent thereon. Therefore, at least the first and third criteria for *prima facie* obviousness are not met. Applicant respectfully submits that a person of ordinary skill in the art at the time of this application would not look into the teachings of Yasushi and modify it to reach the subject matter of the claims at issue. Therefore, no *prima facie* case of obviousness is established. Accordingly, this rejection should be withdrawn.

Moreover, claims 30 and 32-33 are rejected under 35 U.S.C. § 103(a) as being obvious over Yasushi in view of U.S. Patent No. 6,603,061 ("Wallace"); and claim 31 is rejected under 35 U.S.C. § 103(a) as being obvious over Yasushi in view of European Patent No. EP5568334 ("Song"). The deficiencies of Yasushi are addressed above. Like Yasushi, neither Wallace nor Song teaches or suggests a wetting agent coated on the surface of a cross-linked gelatin sponge, and therefore no combination of Wallace or Song with Yasushi teaches or suggests all of the elements of the currently pending claims of the instant application. Consequently, the amended set of claims should not be rendered obvious over Yasushi in view of Wallace or Song.

Accordingly, the obviousness rejections asserted against the aforementioned claims should be withdrawn.

An early action indicating the allowability of this application is respectfully requested. If a telephone call would expedite prosecution of the subject application, the Examiner is invited to call the undersigned attorney. The undersigned verifies that he is authorized to act on behalf of the assignee of the present application.

Dated: June 14, 2007

Respectfully submitted,

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